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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 08/961,083 | 10/30/97 | CHOI G | PB340P2 |

HM32/0930

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| EXAMINER | |
|---|---|
| HINES, J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1641 | |

DATE MAILED: 09/30/98

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 08/961,083 | Choi et al. |
| **Examiner** | **Group Art Unit** |
| Ja-Na Hines | 1641 |

☒ Responsive to communication(s) filed on *Oct 30, 1997*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-21* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, are drawn to an isolated nucleic acid molecule, classified in class 424, subclass 185.1.

II. Claims 5-8, are drawn to a method of making a recombinant vector , classified in class 435, subclass 91.4.

III. Claims 9-10 and 13, are drawn to a method of producing a polypeptide, classified in class 424, subclass 200.1.

IV. Claim 11 is drawn to a polypeptide, classified in class 424, subclass 139.1.

V. Claim 12, is drawn to a polypeptide antigen, classified in class 424, subclass 184.1.

VI. Claims 14-15, are drawn to an antibody and a hybridoma which produces the antibody, classified in class 424, subclass 141.1.

VII. Claim 16, is drawn to a vaccine, classified in class 424, subclass 9.2.

VIII. Claim 17, is drawn to a method of preventing infection, classified in class 424, subclass 900.

IX. Claim 18, is drawn to a method of detecting Streptococcus under conditions such that hybridization occurs, classified in class 435, subclass 6.

X. Claim 19, is drawn to a method of detecting Streptococcus using polymerase chain reaction, classified in class 435, subclass 91.2.

XI. Claim 20, is drawn to a kit for detecting Streptococcus, classified in class 435, subclass 7.92.

XII. Claim 21, is drawn to a method of detecting Streptococcus using antibody-antigen complexes, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions in group II and groups I or IV or V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the use of hybridoma cells to make any of the products in groups I or IV or V as opposed to using the recombinant vector disclosed in group II, therefore these groups are distinct.

3. Inventions in group VI and groups I or IV or V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, making a recombinant vector to produce any of the products in groups I or IV or V will make these invention distinct.

4. Inventions in groups I or IV or V and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the each product could be used as a method of vaccination as opposed to making polypeptides (group III).

5. Inventions in group I or IV or V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each product could be used as a method of producing a polypeptide instead of as a vaccine as disclosed in group VII.

6. Inventions in group I or IV or V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used to detect Streptococcus and not as a method of preventing infection, see group VIII claims.

7. Inventions in group I or IV or V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used to detect Streptococcus with Polymerase Chain Reaction methods, and not with hybridization techniques, see group IX.

8. Inventions in group I or IV or V and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used as detection methods using hybridization and not Polymerase Chain Reaction methods as disclosed in group X.

9. Inventions in groups I or IV or V and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be detected with antibody-antigen complexes and not by the kit method for detection disclosed in group XI.

10. Inventions in group I or IV or V and XII are related as product and process of use. The inventions in this relationship are distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In this case a method of detection can use a kit with a solid support and a detecting means and not antibody-antigen complexes to detect the presence of Streptococcus as disclosed in group XII.

11. Inventions in groups III, VII, VIII, IX, X, XI and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the individual groups each disclose a different use for the products claimed.

12. Inventions in groups II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are claimed in groups II and VI. Group II makes a recombinant vector and group VI makes a hybridoma cell.

13. Inventions in groups I, VI and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case group I's product is an isolated nucleic acid, group IV's product is polypeptide and group V's product is an antigen.

14. Because these inventions are distinct for the reasons given above and the search required for any one of the twelve groups is not required for any of the other groups, restriction for examination purposes as indicated is proper.

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487.

Ja-Na Hines

September 24, 1998

James C. Housel 9/28/98

JAMES C. HOUSEL

SUPERVISORY PATENT EXAMINER